Ivera Medical, Inc.
Don Canal
Vice President RA/QA
2731 Loker Avenue West
Carlsbad, California 92010

March 11, 2022

Re: K140657
Trade/Device Name: Curos Red Port Protector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Don Canal:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 4, 2014 and correction letter dated December 14, 2018. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation 880.5440.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices, 240-402-6029, Payal.Patel@fda.hhs.gov.

Sincerely,

Payal Patel
Assistant Director for General Hospital Devices
DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors
OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

FDA U.S. FOOD & DRUG ADMINISTRATION

December 14, 2018

Ivera Medical, Inc.
Don Canal
Vice President RA/QA
2731 Loker Avenue West
Carlsbad, California 92010

Re: K140657
Trade/Device Name: Curos Red Port Protector
Regulatory Class: Unclassified
Product Code: QBP
Dated: March 14, 2014
Received: March 14, 2014

Dear Don Canal:

This letter corrects our substantially equivalent letter of December 4, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140657

Device Name
Curos Red Port Protector

Indications for Use *(Describe)*
The Curos Red is intended for use on dialysis catheter female Luers and open female ports on stopcocks as a disinfecting cleaner prior to line connection and to act as a cover between line accesses. In three (3) minutes after application, the Curos Red will disinfect the female Luer and act as a cover until removed. The effectiveness of the Ivera Curos Red was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curos Red may be used in the home or healthcare facility.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K140657

General Company Information

Name:	Ivera Medical Corporation
Contact:	Don Canal Vice President Operations RAQA
Address:	Ivera Medical Corporation 3525 Del Mar Heights Road Suite #430 San Diego, CA 92130
Telephone:	972-955-7644
Fax:	858-228-1770
Email:	don.canal@curos.com

Date Prepared: November 4, 2014

General Device Description

The Curos Red Port Protector contains 70% Isopropyl alcohol and is intended for use on dialysis catheter open female luers and open female ports on stopcocks as a disinfecting cleaner prior to line connection and to act as a cover between line accesses. The Curos Red has a highly visible red color that may allow improved compliance monitoring by easy visual verification to ensure that all open female luers are disinfected and covered. The Curos Red may be used in the home or healthcare facility.

Common Name:	**Pad, Alcohol**
Trade Name:	**Curos Red Port Protector**
Classification:	Unclassified Device, product Code LKB

Predicate Devices

K111992 Curos Port Protector, Ivera Medical, Inc.
K101385 Dual Luer Lock Cap, Baxter Healthcare Corporation

Intended Use (Indications)

The Curos Red is intended for use on dialysis catheter female luers and open female ports on stopcocks as a disinfecting cleaner prior to line connection and to act as a cover between line accesses. In three (3) minutes after application,

the Curos Red will disinfect the female luer and act as a cover until removed. The effectiveness of the Ivera Curos Red was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curos Red may be used in the home or healthcare facility.

Comparison with Predicate Device

Subject Device to Predicate Technological Comparison Table

Characteristic	Subject Device	Curos Port Protector K111992	Predicate Device
Device name	Curos Red Port Protector	Curos Port Protector	Dual Luer Lock Cap
Common Name	Alcohol, disinfecting pad	Alcohol, disinfecting pad	IV Administration set
Manufacturer	Ivera Medical	Ivera Medical	Baxter Healthcare Company
510(k) number	Subject Device	K111992	K101385
Regulation number, product code	Unclassified, Preamendment device, product code: LKB	Unclassified, Preamendment device, product code: LKB	IV Administration Set, 21 CFR 880.5440, FPA, Class II
Indications for use	The Curos Red is intended for use on dialysis catheter female Luers and open female ports on stopcocks as a disinfecting cleaner prior to line connection and to act as a cover between line accesses. In three (3) minutes after application, the Curos Red will disinfect the female Luer and act as a cover until removed. The effectiveness of the Curos Red was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curos Red may be used in the home or healthcare facility.	The Curos is intended for use on swab-able luer access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between line accesses. Curos ™ will disinfect the valve three (3) minutes after application and act as a physical barrier to contamination for up to seven (7) days (168 hours) if not removed. The effectiveness of Curos Protectors were tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli and Pseudomonas aeruginosa, Candida glabrata, Candida albicans and was found to have >4 log reduction. The Curos Port Protector may be used in the home or healthcare facility.	The Dual Luer Lock Cap is indicated for use as a cap for male or female ports on medical devices such as manifolds, stopcocks or sets.
Disinfectant – active ingredient	70% Isopropyl Alcohol	70% Isopropyl Alcohol	None

Characteristic	Subject Device	Curos Port Protector K111992	Predicate Device
Male Luer Connection	No	No	Yes
Connection to open female luer connection	Yes	No	Yes
Connection to needleless IV Valve	Yes	No	No
Length	0.47 inches	0.40 inches	0.365
Diameter	0.50 inches	0.54 inches	0.205
User Population	Home and hospital use	Home and hospital use	Home and hospital use
Colorants Used (type, amount, concentration)	Red, molded plastic, 3% concentration	Translucent green, molded plastic, 3% concentration	White Plastic. Exact material formulation and colorant is not available
Provided Sterile	Yes	Yes	Yes
Single Use Device	Yes	Yes	Yes
Plastic Housing to remain in place	Yes	Yes	Yes

Substantial Equivalence Performance Testing

Ivera Medical has provided non-clinical performance test data that demonstrates the pre-defined acceptance criteria for a disinfecting device has been met. This acceptance criteria is defined as a bacteria count reduction of $\geq$ 4 log reduction of 2 selected gram positive bacteria, 2 selected gram negative bacteria, and two selected fungus/yeast micro-organisms for a period of time from 3 minutes. The Efficacy testing methods and organisms are the same as those tested for the Curos Predicate device which was cleared under 510(k) K111992.

The Curos Red device has been tested to meet the requirements of ISO 594-2 testing for sections: ease of assembly, rotational force to remove (un-torque evaluation) and leakage using water under pressure and leakage using vacuum with air. The testing was completed in accordance with Ivera test protocols. Ivera also completed Simulated Clinical Condition Evaluation testing to demonstrate that the Subject device seals and acts as a cover for the port.

The efficacy test results are summarized in Table 1.

Table 1 - Efficacy Test Results

Organism	Acceptance Criteria (bacterial count reduction (ΔLog))	3 minute exposure (bacterial count reduction (ΔLog))
Staphylococcus aureus	**≥4 Log**	**6.7 Log**
Staphylococcus epidermis	**≥4 Log**	**6.9 Log**
Escherichia coli	**≥4 Log**	**6.7 Log**
Pseudomonas aeruginosa	**≥4 Log**	**6.9 Log**
Candida Albicans	**≥4 Log**	**6.5 Log**
Candida Glabrata	**≥4 Log**	**6.8 Log**

The Ivera Curos Red is sterilized using a validated Gamma sterilization process which complies with ISO11137-1:2006/(R) Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose. Recognition number 14-225.

ISO11137-2:2006 Sterilization of health care products – Radiation – Part 1: requirements for development of validation and routine control of sterilization process for medical devices. Recognition number 14-297.

11137-3:2006/(R) 2010 10/04/2010 AAMI ANSI ISO 14-298 - Radiation - Part 3: Guidance on Dosimetric Aspects. Recognition number 14-298.FDA recognized standard ISO11137 Sterilization Standard.

Ivera Medical has completed testing to demonstrate the materials of construction for the Subject Device meet FDA recognized standard ISO10993 for biocompatibility.

Conclusion

The analysis arguments and test results demonstrate the Curos Red device is safe for its intended use and is substantially equivalent to the predicate devices.